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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

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12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,844	HODGE ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,8,18,20-26,29-32,34-41,43-45 and 47-59* is/are pending in the application.

4a) Of the above claim(s) *1,3,4,6,8,18,20-26,29-32,34-39,44 and 49-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,41,43,45,47 and 48* is/are rejected.

7)☒ Claim(s) *40,41,43,45,47 and 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0806*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election, with traverse, of Invention III(B)(D)(E) in their response of August 8, 2008 is acknowledged. The elected invention is directed to a method for identifying an agent that decreases pathogenicity by decreasing Rab11A enzyme activity. Applicants' traversal is based on the following arguments.

(A) The scope of the presently pending claims is narrowed to identifying an agent that decreases pathogenicity of a virus by decreasing Rab11A activity. All types of Rab11A activity, enzymatic or expression, can be included into a single genus, with each type being a species.

(B) Searching "activity" will turn up both enzymatic activity and expression.

These arguments are not found to be persuasive for the following reasons.

(A) As explained in the prior action, methods for detecting modulators of enzymatic activity uses different reagents and steps from methods for detecting modulators of protein expression. Thus, the two methods are distinct.

(B) It is not agreed that searching the term "activity" will identify all art where methods for analyzing Rab11A expression are taught. There are many reports in the literature where protein expression is measured, but no activity is measured. Moreover, measurement of expression includes assessment of recombinant reporter genes, which is not a reflection of enzyme activity.

The restriction requirement is still deemed proper and is therefore made FINAL.

It is acknowledged that with Applicants' response of August 8, 2008, Claims 9, 10, 15-17, and 19 are cancelled and Claims 1, 821-24, 26, 30, 32, 35-37, 40, 43, 44, 49-54, and 58 are amended. Claims 1, 3, 4, 6, 8, 18, 20-26, 29-32, 34-41, 43-45, and 47-59 are pending. Claims 1,

3, 4, 6, 8, 18, 20-26, 29-32, 34-39, 44, 49-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 40, 41, 43, 45, 47, and 48 are hereby examined.

Priority

The priority date granted for the instant invention is February 25, 2005, the filing date of PCT/US05/06396, which disclosed the elected invention. It is noted that none of US 60/547,328, PCT/US2003/037143, US 60/427, or US 60/482,604 disclose Rab11A.

Title

The title is objected to because it is not descriptive of the elected invention.

Drawings-Objections

Figure 3A is objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide sequences with ten or more bases and all amino acid sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Abstract

The abstract is objected to because there are two versions filed on the same date. It is unclear which version is to be used.

Specification-Objections

The specification is objected to for disclosing sequences, for example on page 23, that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide sequences with ten or more bases and all amino acid sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Claims-Objections

Claims 40, 41, 43, 45, 47, and 48 are objected to for encompassing non-elected subject matter.

Claim 43 is objected to for "or a Rab11A modulator that affects Rab11A activity", which should be corrected to "or is a Rab11A modulator that affects Rab11A activity"

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 41, 43, and 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 40, the phrase "Rab11A target" renders the claim indefinite. It is unclear whether said phrase means Rab11A itself, a substrate of Rab11A, a binding partner of Rab11A, or something else. The skilled artisan would not know the metes and bounds of the recited invention. Claims 41, 43, and 45-48, as dependent from Claim 40, are indefinite for the same reason. For purposes of examination, it is assumed that "Rab11A target" means Rab11A itself .

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 40, 41, 43, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the method rendered obvious by Brock et al, 2003 in view of Gibbs et al, 1990 (see rejection under 35 USC 103(a) below), does not reasonably provide enablement for any method of identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement

and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 40, 41, 43, and 45 are so broad as to encompass any method of identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic GTPase activity. Claim 47 is so broad as to encompass any method of identifying an agent that decreases pathogenicity of any pathogen that is an enveloped virus, wherein the method measures a decrease in Rab11A enzymatic GTPase activity. Claim 48 is so broad as to encompass any method of identifying an agent that decreases pathogenicity of any pathogen that is an envelope RNA virus, wherein the method measures a decrease in Rab11A enzymatic GTPase activity. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods broadly encompassed by the claim.

The specific reagents and steps used for any method determine the methods success. In the instant case, predictability of which steps and reagents can be used to obtain the desired identification of agents that decrease pathogenicity of any pathogen requires a knowledge of, and guidance with regard to how any pathogen's effects are mediated by Rab11A and how any steps and reagents relate to the desired identification of agents that decrease pathogenicity of any pathogen. However, in this case the disclosure fails to provide enablement for any method of

identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic GTPase activity.

While methods for determining if a pathogen acts via Rab11A are known in the art, it is not routine in the art to screen an essentially unlimited number of pathogens for pathogenicity via Rab11A. Without knowing whether a particular pathogen acts via Rab11A, any result from measuring the effect of a test agent on Rab11A enzymatic GTPase activity cannot predict an effect of the test agent on the pathogenicity of the pathogen. Furthermore, the identity of pathogens that act via Rab11A is not predictable. Thus, the artisan is reduced to trial and error testing of every possible pathogen for pathogenicity via Rab11A.

The specification does not support the broad scope of Claims 40, 41, 43, and 45, which encompasses all methods of identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic activity. The specification does not support the broad scope of Claim 47, which encompasses all methods of identifying an agent that decreases pathogenicity of any pathogen that is an enveloped virus, wherein the method measures a decrease in Rab11A enzymatic activity. The specification does not support the broad scope of Claim 48, which encompasses all methods of identifying an agent that decreases pathogenicity of any pathogen that is an envelope RNA virus, wherein the method measures a decrease in Rab11A enzymatic activity. The specification does not support the broad scope of Claims 40, 41, 43, 45, 47, and 48 because the specification does not establish: (A) pathogens for which pathogenicity is mediated by Rab11A GTPase enzymatic activity; (B) a rational and predictable scheme for determining the pathogens for which pathogenicity is mediated by

Rab11A GTPase enzymatic activity; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of methods for identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 40, 41, 43, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 40, 41, 43, 45, 47, and 48 are directed to a genus of methods for identifying an agent that decreases pathogenicity of any pathogen, wherein the method measures a decrease in Rab11A enzymatic GTPase activity. The specification teaches no such methods. Given this lack of description of representative species encompassed by the genera of the claims, the specification fails to sufficiently describe the

claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40, 41, 43, 45, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brock et al, 2003 in view of Gibbs et al, 1990, as evidenced by Marty et al, 2004. Brock et al teach a method for identifying agents, myosin Vb tail and Rab11-FIP1, which decrease pathogenicity of RSV by contacting the agents with Rab11A, wherein the method measures RSV replication (Fig 2&6). Brock et al does not teach a method for identifying agents that decrease pathogenicity of RSV by contacting the agents with Rab11A, wherein the method measures Rab11A enzymatic GTPase activity. Gibbs et al teach a method for measuring enzymatic GTPase activity using immunoprecipitation followed by chromatography (pg 20438, pargs 5-7; Fig 1-3). It would have been obvious to a person of ordinary skill in the art to combine the teachings of Brock et al and Gibbs et al to develop a method for determining whether the agents myosin Vb tail, Rab11-FIP1, and other test agents decrease pathogenicity of RSV by contacting the agents with Rab11A, wherein the method measures Rab11A enzymatic GTPase activity. Motivation to do so is provide by the desire to determine if the agents decrease pathogenicity of RSV by directly affecting Rab11A enzymatic GTPase activity. The expectation of success is high, as methods for measuring GTPase activity are known in the art. It is noted that

Marty et al teach that RSV hijacks lipid rafts (Abstract). Therefore, Claims 40, 41, 43, 45, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brock et al, 2003 in view of Gibbs et al, 1990, as evidenced by Marty et al, 2004.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652